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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/774,557	01/31/2001	Michell Anthony DeLong	7998	4943

27752 7590 11/26/2004

THE PROCTER & GAMBLE COMPANY
INTELLECTUAL PROPERTY DIVISION
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EXAMINER

BADIO, BARBARA P

ART UNIT	PAPER NUMBER
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1616

DATE MAILED: 11/26/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No. 09/774,557	Applicant(s) DELONG ET AL.	
	Examiner Barbara P. Badio, Ph.D.	Art Unit 1616	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
 - If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
 - If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
 - Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☐ Responsive to communication(s) filed on ____.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-15 is/are pending in the application.
- 4a) Of the above claim(s) 5-7 is/are withdrawn from consideration.
- 5) ☐ Claim(s) ____ is/are allowed.
- 6) ☒ Claim(s) 1-4 and 8-15 is/are rejected.
- 7) ☐ Claim(s) ____ is/are objected to.
- 8) ☐ Claim(s) ____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on ____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
 Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
 Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. ____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|--|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. ____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date <u>9/17/04</u> . | 6) <input type="checkbox"/> Other: ____ |

Final Office Action on the Merits

1. The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

Status of the Application

2. Claims 1-15 are pending in the present application. Claims 5-7 stand withdrawn as being drawn to a nonelected species.

Claim Rejections - 35 USC § 102

3. The rejection of claims 1-4, 8-11, 13 and 15 under 35 USC 102(b) over Johnstone (WO 98/33497) is withdrawn.
4. The rejection of claims 1-4, 8-10 and 13 under 35 USC 102(b) over Wos et al. (WO 99/12895) is withdrawn.
5. Claims 1-3, 10 and 13 are rejected under 35 U.S.C. 102(b) as being anticipated by Skuballa et al. (US 4,004,020).

Skuballa et al. teach prostanoic acid derivatives, such as 9,11,15-trihydroxy-15-(1,3-dioxa-2-indanyl)-16,17,18,19,20-pentanor-prostenoic acid, useful in triggering abortions and synchronizing the conception cycle of mammals (see the entire article, especially col. 3, lines 1-47; col. 11, lines 1-64; Examples 20-22; claims 1-5, 12, 14 and

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27-29). The reference teaches (a) various routes of administration including oral administration; (b) dosage range of the compound for administration and (c) the use of customary auxiliary agents and vehicles such as ethanol and ethylene glycol for production of various formulations (see especially col. 11, lines 38-64). The composition taught by the reference is encompassed by the instant claims.

6. Claims 1-4, 8-10, 13 and 14 are rejected under 35 U.S.C. 102(b) as being anticipated by Vorbrueggen et al. (US 4,217,360).

Vorbrueggen et al. teach 1,3-benzodioxaneprostanoic acid derivatives such as 9,11,15-trihydroxy-15-(1,3-benzodioxan-2-yl)-16,17,18,19,20-pentanorprostenoic acid and the methyl ester thereof as well as their use for inducing menstruation, interrupting pregnancy, inducing labor and synchronizing the sexual cycle in female mammals (see the entire article, especially col. 1, line 30 – col. 2, line 16; col. 7, lines 4-12; Examples 31-35 and claims 1-4, 7, 11-13, 45-50, 57-62 and 75). The reference also teaches (a) various routes of administration such as inhalation, oral administration; (b) various carriers such as water, vegetable oils, polyethylene glycols, gelatin, talc, freon, ethanol and propylene glycol and (c) dosage range of the compound for administration (see col. 8, line 1 – col. 9, line 2). The composition taught by the reference is encompassed by the instant claims.

Claim Rejections - 35 USC § 103

7. The rejection of claims 1-4 and 8-15 under 35 USC 103(a) over Johnstone (WO 98/33497) is withdrawn.

8. The rejection of claims 1-4 and 8-15 under 35 USC 103(a) over Wos et al. (WO 99/12895) is withdrawn.

9. Claims 1-4 and 8-15 are rejected under 35 U.S.C. 103(a) as being unpatentable over Skuballa et al. (US 4,004,020).

Skuballa et al. teach prostanoic acid derivatives, such as 9,11,15-trihydroxy-15-(1,3-dioxa-2-indanyl)-16,17,18,19,20-pentanor-prostenoic acid, useful in triggering abortions and synchronizing the conception cycle of mammals (see the entire article, especially col. 3, lines 1-47; col. 11, lines 1-64; Examples 20-22; claims 1-5, 12, 14 and 27-29). The reference teaches (a) various routes of administration including oral administration; (b) dosage range of the compound for administration and (c) the use of customary auxiliary agents and vehicles such as ethanol and ethylene glycol for production of various formulations (see especially col. 11, lines 38-64).

The instant claims differ from the reference by reciting additional compounds not exemplified by Skuballa et al. However, it would have been obvious to one having ordinary skill in the art at the time of the present invention to make any of the species of prostanoic acid derivatives of the genus taught by Skuballa, including those of the instant claims, with the reasonable expectation that any of the species of the genus

would have similar properties, and, thus, the same use as the genus as a whole. The motivation is based on the desire to make additional compounds useful in triggering abortions and synchronizing conception as taught by the reference.

Claims 11, 12, 14 and 15 differ from the reference by reciting specific excipients not exemplified by Skuballa et al. However, (a) the excipients recited by the instant claims are known in the art and (b) the formulation of preparations containing the compounds and various excipients, including those of the instant claims, are within the level of skill of the ordinary artisan in the pharmaceutical art. Thus, the utilization of the specific carriers recited by the instant claims would be prima facie obvious to the skilled artisan.

10. Claims 1-4 and 8-15 are rejected under 35 U.S.C. 103(a) as being unpatentable over Vorbrueggen et al. (US 4,217,360).

Vorbrueggen et al. teach 1,3-benzodioxaneprostandoic acid derivatives such as 9,11,15-trihydroxy-15-(1,3-benzodioxan-2-yl)-16,17,18,19,20-pentanoic acid and the methyl ester thereof as well as their use for inducing menstruation, interrupting pregnancy, inducing labor and synchronizing the sexual cycle in female mammals (see the entire article, especially col. 1, line 30 – col. 2, line 16; col. 7, lines 4-12; Examples 31-35 and claims 1-4, 7, 11-13, 45-50, 57-62 and 75). The reference also teaches (a) various routes of administration such as inhalation, oral administration; (b) various carriers such as water, vegetable oils, polyethylene glycols, gelatin, talc, freon, ethanol

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and propylene glycol and (c) dosage range of the compound for administration (see col. 8, line 1 – col. 9, line 2).

The instant claims differ from the reference by reciting additional compounds not exemplified by Vorbrueggen et al. However, it would have been obvious to one having ordinary skill in the art at the time of the present invention to make any of the species of 1,3-benzodioxaneprostanoic acid derivatives of the genus taught by Vorbrueggen, including those of the instant claims, with the reasonable expectation that any of the species of the genus would have similar properties, and, thus, the same use as the genus as a whole. The motivation is based on the desire to make additional compounds useful for inducing menstruation, interrupting pregnancy, inducing labor and synchronizing the sexual cycle in female mammals as taught by the reference.

Claims 11, 12 and 15 differ from the reference by reciting excipients not exemplified by Vorbrueggen et al. However, (a) the excipients recited by the instant claims are known in the art and (b) the formulation of preparations containing the compounds and various excipients, including those of the instant claims, are within the level of skill of the ordinary artisan in the pharmaceutical art. Thus, the utilization of the specific carriers recited by the instant claims would be prima facie obvious to the skilled artisan.

Conclusion

11. Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP

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§ 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

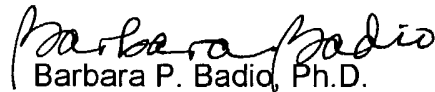
Telephone Inquiry

12. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Barbara P. Badio, Ph.D. whose telephone number is 571-272-0609. The examiner can normally be reached on M-F from 6:00am-3:30pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Gary L. Kunz can be reached on 571-272-0887. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

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Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).


Barbara P. Badio, Ph.D.
Primary Examiner
Art Unit 1616

BB
November 23, 2004